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Knee Biofeedback Rehabilitation Interface for Game-based Home Therapy ("KneeBRIGHT") Phase II

Protocol

Osteoarthritis (OA) is the leading cause of disability in the United States. As osteoarthritis is associated with the lower limb muscle weakness, rehabilitation focused on quadriceps and other lower extremity muscle strengthening is a well-established treatment for patients with knee OA. However, patient adherence to exercise routines is low due to the lack of guidance regarding optimal protocols, and poor engagement during the repetitive routines that patients find tedious and boring.

Long-term goal of this study is to improve knee OA outcomes through effective and motivating rehabilitation exercises. The Knee Biofeedback Rehabilitation Interface for Game-based Home Therapy ("KneeBRIGHT") system combines electromyography (EMG) biofeedback with video game therapy (VGT) to provide knee OA patients with an engaging, effective tool for conducting rehabilitation exercises at home. KneeBRIGHT aims to motivate patients with knee OA to conduct regular muscle strengthening exercise through an engaging, EMG-driven video game therapy.

Participants with age from 40-75, with independent ambulation and with the diagnosis of knee OA made by x-ray and a score of at least 2 (out of 4) on the Kellgren-Lawrence OA radiographic classification system will be included in the study. Participants with psychiatric or cognitive impairment (e.g., dementia), symptomatic spine, hip, ankle, or foot disease other than OA that would interfere with assessment of the knee will be excluded. Participants with balance or vestibular disorders, peripheral neuropathy, skin conditions that prevent EMG electrode placement, prisoner, pregnant women (by report), non-English-speaking, individuals who are visually and/or hearing impaired will also be excluded.

Eligible participants will be randomized to two groups: (1) KneeBRIGHT group; (2) Standard rehabilitation group. Both groups will undergo baseline and follow up assessment to measure the patient-reported outcomes, thigh muscle strength, and balance. Participants in both groups will undergo a 12-week program including 3 exercise sessions per week that includes a combination of in-person and at home sessions (Table 1).

Table 1 Study schedule for participants visits over 12 weeks

	Visit 1 (Screening)	Visit 2 (Baseline)	Visit 3-38	Follow-up
Study Week	0	0	1-12	13
Informed Consent	x			
Review study eligibility	x	x		
Medical History	x			
Strength, Balance & Endurance testing		x		
Questionnaires		x		x
Rehabilitation Exercises			x	x

Both groups will undergo same rehabilitation protocol which will begin with sessions supervised in the clinic by the study team physical therapist and gradually home sessions will be added. Participants in KneeBRIGHT group will perform the quadriceps strengthening exercises with the video-games based activities. The EMG biofeedback units and video game w/laptop will be provided to the subjects for home use. Subjects will receive instruction on how to apply the EMG biofeedback unit and use of the video game. KneeBRIGHT Game Activities consists of an introduction of the player to the virtual world and the missions, the player customizes the personal avatar and completes a series of calibration contractions and practice exercises to gain familiarity with the game controls. Through the EMG system, a player's muscle contractions translate into physical movements of the avatar and control of vehicles within the virtual environment. Each quest-type challenge is designed to permit play in a seated, supine, supported standing, or freestanding position, based on an individual's physical status. User interactions with the game incorporate knee extension exercises and functional movements that provide optimal therapeutic benefits.

Participants in both groups will undergo combination of home and in clinic sessions. Protocol will start with six clinic visits in order to maximize familiarity with the exercise routines and equipment. Home sessions will be added after 2 weeks in rehabilitation (Table 2). The sessions will consist of warm up, strengthening, balance, precision and gentle stretching exercises. Strengthening exercises will be focused on quadriceps, hamstring, calf and gluteal muscles. Stretching exercises will be focused on quadriceps, hamstring and calf muscles. Progression will be guided by the rehabilitation principles and participants response to the exercise. The amount of these exercises will depend on how they make the subject feel. The rehabilitation program will allow the subject to increase the amount of exercise they can perform. Exercises will be limited if the subject feels discomfort. Overall, protocol will consist of 36 sessions in total, 20 in clinic sessions and 16 home-based sessions.

Table 2 Weekly schedule for patients for in clinic and home-based therapy sessions

	One Hour Exercise Sessions	
	In clinic session	Home-based session
Week 1	3	0
Week 2	3	0
Week 3	2	1
Week 4	2	1
Week 5	2	1
Week 6	2	1
Week 7	1	2
Week 8	1	2
Week 9	1	2
Week 10	1	2
Week 11	1	2
Week 12	1	2
TOTAL	20	16

Pre and post intervention outcome measures will be compared to explore the effectiveness. Technology acceptance will also be studied in patients randomized to KneeBRIGHT group.

Overall, KneeBRIGHT has the potential to significantly enhance OA rehabilitation by improving functional recovery through physical practice of specific, adaptive exercise and promoting adherence through fun games and performance feedback. Use of the KneeBRIGHT system in teletherapy may increase access to remote/underserved areas and extend the range of existing rehabilitation facilities.

Statistical analysis

Knee function assessed by composite KOOS score prior to the study will be compared to the KOOS score recorded post-intervention to test the primary hypothesis that patients conducting the KneeBRIGHT exercise will significantly improve knee function compared to the control group. Pre-intervention KOOS scores measures will be subtracted from the post-intervention scores to produce a set of delta values. These delta values will be analyzed via Analysis of Covariance (ANCOVA). A $p \leq 0.05$ decision rule will be utilized as the rejection criterion.

Questionnaire results will be used to test the hypothesis that patients using the KneeBRIGHT system demonstrate increased levels of engagement compared to those conducting a conventional exercise routine. The questionnaire scores will be tallied to produce composite scores. These composite scores will be analyzed via a linear mixed model. A $p \leq 0.05$ decision rule will be used as the null hypothesis rejection criterion.

Timing data from the home visits will be analyzed by comparing the minutes of exercise with the KneeBRIGHT system to minutes of exercise with the standard exercise regimen in the control group to

test the hypothesis that exercise duration is greater with the KneeBRIGHT system. Mean usage time on each system will be analyzed via Student's paired t -test, with $p \leq 0.05$ as the null hypothesis rejection criterion.